STATEMENT BY

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DIVISION OF DRUG MARKETING, ADVERTISING AND COMMUNICATIONS

CENTER FOR DRUG EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE, AND TOURISM

SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

JULY 24, 2001

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Nancy Ostrove, Deputy Director of the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA or the Agency). DDMAC regulates prescription drug promotion and helps ensure that FDA-regulated industry complies with the applicable provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act and implementing regulations.

I am here today to talk about promotion that manufacturers of prescription drugs (product sponsors) direct toward consumers and patients. This is referred to as "direct-to-consumer" promotion or DTC. Such promotion uses multiple avenues for reaching lay audiences, including, but not limited to: television and radio advertisements, print advertisements, telephone advertisements, direct mail, videotapes and brochures.

It is important to understand the scope of FDA's authority in this area. It is also important to understand the different types of advertisements that are directed toward consumer audiences.

STATUTORY AND REGULATORY AUTHORITY

The FD&C Act and regulations do not distinguish between professional and consumer audiences. Section 502(n) of the

FD&C Act specifies that prescription drug advertisements must contain "a true statement of . . . information in brief summary relating to side effects, contraindications, and effectiveness" of the advertised product. The implementing regulations
(Title 21, Code of Federal Regulations [CFR] Section 202.1), originally issued in the 1960s, specify, among other things, that prescription drug advertisements cannot be false or misleading, cannot omit material facts, and must present a fair balance between effectiveness and risk information. Further, for print advertisements, the regulations specify that every risk addressed in the product's approved labeling must also be disclosed in the advertisements.

For broadcast advertisements, however, the regulations require ads to disclose the most significant risks that appear in the labeling. The regulations further require that the advertisement either contain a summary of "all necessary information related to side effects and contraindications" or provide convenient access to the product's FDA-approved labeling and the risk information it contains.

Finally, the FD&C Act specifically prohibits FDA from requiring prior approval of prescription drug advertisements, except under extraordinary circumstances. Also, the advertising provisions of the FD&C Act do not

address the issue of drug product cost.

TYPES OF ADVERTISEMENTS

There are three different types of ads that product sponsors use to communicate with consumers: "product-claim" advertisements, "help-seeking" advertisements, and "reminder" advertisements. Advertisements that include both a product's name and its use, or that make any claims or representations about a prescription drug, are known as "product-claim" advertisements. These ads must include a "fair balance" of risks and benefits. In addition, they must provide all risk information included in the product's FDA-approved labeling or, for broadcast advertisements, provide convenient access to this information. In our regulations, the phrase "adequate provision" is used to identify the convenient access option. Unlike the "product claim" ads, "help-seeking" advertisements and "reminder" ads need not include any risk information.

A "help-seeking" advertisement discusses a disease or condition and advises the audience to "see your doctor" for possible treatments. Because no drug product is mentioned or implied, this type of ad is not considered to be a drug ad and FDA does not regulate it.

The second type of advertisement that does not need to include risk information is called a "reminder"

advertisement. The regulations specifically exempt this type of ad from the risk disclosure requirements. Like "help-seeking" ads, the "reminder" ad is limited, although in a different way from "help-seeking" ads. "Reminder" ads are allowed to disclose the name of the product and certain specific descriptive (e.g., dosage form) or cost information, but they are not allowed to give the product's indication or dosage recommendation, or to make any claims or representations about the product. The exemption for "reminder" ads was included in FDA's regulations for promotions directed toward health care professionals, who presumably knew both the name of a product and its use. "Reminder" ads serve to remind health care professionals of a product's availability. They specifically are not allowed for products with serious warnings (called "black box" warnings) in their labeling.

EVOLUTION OF DTC PROMOTION

Prior to the early 1980s, prescription products were not promoted directly to consumers and patients. Instead, product sponsors often produced materials that were given to health care professionals to pass on to patients if they thought this would be appropriate for particular patients. In the early 1980s, a few companies started advertising products directly to patient audiences (specifically, older people concerned about pneumonia and people taking

prescription ibuprofen to treat arthritis pain). As a result of questions and concerns about

promotion directed toward non-health care professionals, in 1983 FDA requested that sponsors suspend DTC ads to give the Agency time to study the issue.

The industry complied with this request, and during the ensuing moratorium FDA conducted research and sponsored a series of public meetings. In 1984, the University of Illinois and Stanford Research Institute jointly sponsored a symposium to discuss consumer-directed prescription drug advertising from a broad research and policy perspective. On September 9, 1985, FDA withdrew the moratorium in a Federal Register (FR) Notice (50 FR 36677), which stated that the "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers."

During the early 1990s, product sponsors increasingly used consumer magazines to advertise their products. These ads typically included a promotional message together with the "brief summary" of adverse effects, similar to that used in physician directed ads. The "brief summary" statement, which frequently appears in small print, is not very consumer friendly. In the 1990s, product sponsors also

started using television advertisements in a limited fashion. Television advertisements were limited because FDA and industry did not believe that it was feasible to disseminate the product's approved labeling in connection with the ad. The extensive disclosure needed to fulfill this requirement essentially precluded the airing of such ads. For example, one way to satisfy this requirement would be to scroll the "brief summary," which would take a minute or more even at a barely readable scrolling rate. The industry, therefore, resorted to television ads that did not require risk disclosure.

By the mid-1990s, product sponsors started placing "reminder" ads on television. Because these ads only mentioned the name of the drug, however, they were extremely confusing to consumers, who, unlike health care professionals, were not knowledgeable about the name and the use for these products.

In response to increasing consumer demand for information, FDA began to consider whether broadcast advertisements could be constructed to ensure access to product labeling, the only alternative to including all of an advertised product's risk information. FDA considered suggestions about providing access to multiple sources of product labeling as a means of satisfying the requirement that consumers have

convenient access to FDA-approved labeling when manufacturers broadcast a "product-claim" advertisement.

In August 1997, FDA issued a draft guidance entitled: "Guidance for Industry: Consumer-Directed Broadcast Advertisements" that clarified the Agency's interpretation of the existing regulations. The Guidance described an approach for ensuring that audiences exposed to prescription drug advertisements on television and radio have convenient access to the advertised product's approved labeling. The proposed mechanism consisted of reference in the broadcast advertisement to four sources of labeling information: a toll-free telephone number, a website address, a concurrently running print advertisement, and health care professionals. Following a comment period, and detailed review and consideration of the comments, FDA made only minor changes to the draft guidance, and issued it in final form in August 1999 (64 FR 43197, also found at *www.fda.gov/cder/guidance/1804fnl.htm*). In announcing the final guidance, FDA advised that the Agency intended to evaluate the impact of the guidance, and of DTC promotion in general, on the public health, within two years of finalizing the guidance.

STAKEHOLDER PERSPECTIVES

A number of stakeholder groups have expressed strong interest in DTC promotion. Those that are positive about

DTC promotion assert that this practice will:

- Improve consumers' knowledge of drugs and drug availability.
- Encourage consumers to talk with their health care providers about their health problems.
- Allow consumers and patients to have a greater role in decisions about their own health care that they say they desire.
- Improve communication between patients and their physicians.
- Improve appropriate prescribing by allowing physicians to get more information about their patients from their patients.
- Lower the cost of prescription drugs.

Not all stakeholders are positive about DTC promotion. Opponents assert that DTC advertising will:

- Confuse consumers about drugs.
- Make it appear that prescription drugs are safer than they are.
- Interfere with the patient-physician relationship because patients will insist that their physicians prescribe the advertised products.
- Increase inappropriate prescribing.
- Raise the cost of prescription drugs.

Finally, there is a group of stakeholders with a less polarized view of DTC promotion. They believe that such promotion has both benefits and risks, but that it should be strictly regulated, and that, preferably, all DTC materials

should be "pre-approved" by FDA. They often assert that there are potential public health benefits associated with patients visiting health care providers about untreated diseases or conditions, particularly those that appear to be under treated in the population and that are responsible for long-term harm (for example, high cholesterol, high blood pressure, diabetes and osteoporosis).

CURRENT SITUATION

FDA recognizes that drug promotion raises certain issues for health care professionals and different issues for consumers, in light of differences in medical and pharmaceutical expertise. For this reason, FDA has monitored DTC promotion, and especially broadcast promotion, very closely to help ensure that adequate contextual and risk information, presented in understandable language, is included to fulfill the requirement for fair balance and to help the consumer accurately assess promotional claims and presentations.

Product sponsors of prescription advertisements are required to submit their promotional materials to FDA around the time these materials are initially put into public use. FDA receives approximately 32,000 of these submissions per year, for all types of promotion, including promotion to health care professionals. Product sponsors also can submit draft materials to FDA for review and comment prior to using them.

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DDMAC has made it a high priority to provide comments to product sponsors on voluntarily submitted draft broadcast advertisements within a reasonable time. In fact, although it is not required, a majority of product sponsors voluntarily submit their broadcast advertisements to DDMAC for prior review and comment at some point as advertising materials are being
produced. Product sponsors may ask for review and comment at the very initial stages of production (by supplying the words they intend to use along with rough drawings of their proposed graphics), or at the later stages of final videotape production. DDMAC only gives final comments on final videotapes because inappropriate presentations can turn an otherwise acceptable advertisement into an unacceptable one (for example, by pacing the risk disclosure too rapidly, including multiple distracting visual images during the risk disclosure, or including images that overstate the efficacy of the product beyond what is supported by substantial clinical evidence).

Since January 1997, sponsors of about 65 prescription drugs have aired "product-claim" advertisements on television or radio. A small number of prescription biological products also have been advertised. Nine products fall into the allergy category (nasal and ocular anti-histamines, and nasally administered corticosteroids), while another eight products treat skin or hair-related problems (acne, cold

sores, rosacea, baldness, unwanted facial hair, nail fungus). More importantly, ten products are designed to treat diseases that are believed to be under treated, including high cholesterol and heart disease, and mental health problems like depression. Five products to treat or prevent osteoporosis or menopausal symptoms have been advertised. Other advertised products are

approved to treat such conditions or diseases as asthma, Alzheimer's Disease, arthritis, chronic obstructive pulmonary disease, diabetes, insomnia, migraine, obesity, overactive bladder, serious heartburn, smoking cessation, and sexually transmitted diseases. Most of these are serious problems where patients are in the best position to recognize symptoms.

It is important to note that DDMAC does not know how many different advertisements have aired in broadcast media for these 65 drugs. There have been multiple campaigns for a number of the products, including the allergy and high cholesterol products. In addition, many campaigns include different length "product-claim" commercials, as well as multiple short "reminder" commercials. DDMAC does not track the number of different broadcast advertisements that are submitted. Further, because "help-seeking" advertisements, if done properly, are not considered to be drug ads, most product sponsors do not send them to DDMAC under the

submission requirements for prescription drug promotional materials. Therefore, we have no measure of how many of these have been in the public domain.

ENFORCEMENT RELATED TO DTC PROMOTION

Since 1997 FDA has issued:

- 30 "untitled" (or "Notice of Violation") letters on "product-claim" broadcast advertisements. Such letters request that the violative promotion be stopped immediately. Product sponsors virtually always comply immediately with this request.
- 3 "warning letters" on broadcast advertisements. This is a higher-level enforcement action, and requests that a remedial campaign be conducted by the company to correct the impressions left by the ad.
- 12 "untitled" letters on purported "reminder" broadcast advertisements.
- 3 "untitled" letters on purported "help-seeking" broadcast advertisements.

Most of the violations cited were because the ad overstated or guaranteed the product's efficacy, expanded the indication or the patient population approved for treatment, or minimized the risks of the product, through either

inadequate presentation or omission of information.

Since January 1997, the Agency has issued:

- 44 "untitled" letters that addressed DTC print advertisements or other promotional materials, including purported "reminder" and "help-seeking" materials.
- 1 "warning letter" for a specific DTC print advertisement, and 1 "warning letter" that included a DTC print advertisement as part of an overall misleading campaign.

Generally, the violations involving print ads making "product-
claim" ads were similar to those cited above. Nearly all "reminder" ad violations were the result of representations about the product that triggered the need for full disclosure of benefits and risks. "Help-seeking" ad violations were due to a particular product being implied in the message. As noted above, however, FDA cannot determine how many specific advertisements serve as the denominator for assessing how many have resulted in enforcement action compared with those that have not.

RESEARCH ON DTC PROMOTION

A number of groups have been conducting research on DTC promotion. Much publicly available research consists of

surveys utilizing samples of consumers or patients to examine attitudes about DTC promotion and self-reported behaviors related to DTC promotion in the context of patient-physician visits and use of prescription drugs. The groups sponsoring this research include: Prevention magazine, TIME Inc., the National Consumers League, and American Association of Retirement People. Partial results of a few surveys of physicians have been made publicly available. FDA remains concerned, however, about the representativeness of the physician survey sample.

In 1999, FDA sponsored a telephone survey that focused on a national probability sample of patients who had seen a physician for a problem of their own within the three months prior to the survey. The results of this patient survey suggested that patients are seeking additional information as a result of DTC promotions that they have seen. This information was sought primarily from health care professionals, and secondarily from reference texts and family. Generally, between 10 and 20 percent of respondents said that they sought additional information from the sources referenced in broadcast advertisements - toll-free telephone numbers, websites, and print advertisements. A major result, and one that is consistent with results of Prevention's national surveys, is that a significant minority of respondents said that a DTC ad has caused them to ask a doctor about a medical condition or illness they

had not previously discussed. This could represent a significant and positive public health benefit, particularly if these patients are talking about undiagnosed heart disease or other serious disorders.

The survey results also suggest that DTC advertisements are not significantly increasing visits to a physician's office. For the most part, patients said that they had recently visited their doctors for the traditional reasons: because it was time for a check-up (53 percent), because they were feeling ill (42 percent), or because they had a sudden symptom or illness (41 percent). Only two percent said that they had visited their doctor because of something they had seen or heard. Of those patients who had a conversation with their doctor about a prescription drug: 81 percent said that their doctor had welcomed the question, 79 percent said that their doctor discussed the drug with them, and 71 percent said that their doctor had reacted as though the conversation was an ordinary part of the visit. Only four percent said that their doctor seemed upset or angry when the patient asked about a prescription drug. According to the patients, therefore, physicians seem to be reacting well to questions about prescription drugs. Finally, only 50 percent of these patients said that their doctor gave them the medication discussed. Thirty-two percent said that the doctor

recommended a different drug. Twenty-nine percent of the respondents indicated that behavioral or lifestyle changes were suggested by the doctor. It therefore appears, from FDA's patient survey, that physicians are comfortable denying prescriptions when the prescription would not be right for the patient.

A small number of patients who were denied prescriptions said that their doctors told them why. Reasons included: the drug was not right for the patient; the doctor wanted the patient to take a different drug; the drug had side effects of which the patient was unaware; the patient did not have the condition treated by the drug; the patient did not need a prescription drug; the patient could use a non-prescription drug; and, there was a less expensive drug available.

Patients also were asked about their attitudes concerning prescription drug advertisements. Their answers indicated somewhat mixed feelings. Eighty-six percent agreed that these ads help make them aware of new drugs, 70 percent agreed that the ads give enough information to help the patient decide if they should discuss the product with a doctor, and 62 percent agreed that ads help the patients have better discussions with their doctors about their health. Only 24 percent agreed that DTC ads make it seem like a doctor is not needed to decide whether a drug is

right for someone. In contrast, 58 percent agreed that DTC ads make drugs seem better than they really are, 59 percent agreed that ads do not give enough information about the advertised product's risks and negative effects, and 49 percent agreed that these ads do not give enough information about the benefits and positive effects of the advertised product.

NEXT STEPS

In issuing both the draft and the final broadcast advertisement guidance, FDA stated its intent to assess the impact of the guidance, and of DTC promotion in general, on the public health. FDA is also aware that privately funded research is being planned to examine the effects of DTC promotion. At present, FDA is not aware of any evidence that the risks of DTC promotion outweigh its benefits. FDA intends to carefully examine all available data, to determine whether the public health is adequately protected.

This concludes my prepared remarks. I will be glad to answer any questions you may have on this topic.